Utah Department of Health

CLINICAL LABORATORY BULLETIN November 2008

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING

Lou Anna Arnold	Sample Receiving
Jeff Haslip	Sample Receiving

NOTEWORTHY

✓ **Dipstick a spun urine?** In the September 2008 issue of MLO, a reader asked if it were alright to spin a grossly bloody urine in order to do a dipstick urinalysis. The response from the team at Mayo Clinic's Renal Function Laboratory was – no. They consulted their dipstick manufacturer (Siemens Medical) who said the color from the hemoglobin in the supernatant would interfere with the color on some pads. Using a spun urine, even when not bloody, would affect the red blood cell and leukocyte esterase tests as all the cells would be at the bottom of the tube.

✓ **Histology – handling those "fatty" specimens:** Bing Miller, PA(ASCP) offered a suggestion on how to improve fatty breast specimen sectioning in the August 2008 issue of Lab Medicine. The author rapidly cooled 721 blocks by direct immersion in an isopentane bath. Mark Brownell, MD of Grant/Riverside Hospital in Ohio found no specimens from the 721 blocks that required reprocessing. Dr. Brownell also saw no interference with immunohistochemistry stains, estrogen receptors (ER), progesterone receptors (PgR), or HER2/neu testing. For the entire article go to www.labmedicine.com.

✓ **Repeat sample acceptable variance for whole blood glucose:** Bradley S. Karon, MD, PhD, Mayo Clinic Director of Hospital Clinical Laboratories responded to a reader's question in the September 2008 issue of MLO. How close is close enough? Dr. Karon feels the available studies show good precision from sample to sample on the same glucose meter. Usually the results are < 5% apart even at high levels.

If your observed variance is >5%, consider capillary sampling errors, specimen interference or simply the accuracy of your particular meter as the error source. There is greater variation between whole blood meter measurements and laboratory-plasma reference values in a hospital setting. This variance can be as high as 10% or more for some meters.

To determine if you have a "bad" meter, Dr. Karon suggests you test the meter with a pooled blood sample spiked with glucose at the low, normal and high range. Run the same "standard" on your meter several times and calculate the %CV from the mean. You may ask your reference lab to send you the samples and do the calculations. If the instrument is precise, you can focus on collection technique.

CONTENTS

See complete article at www.mlo-online.com.

✓ **hCG – know the limitations:** David G. Grenache, PhD, at ARUP presented "HCG: Beyond a test for pregnancy" at the USCLS Spring Seminar in April 2008. Dr. Grenache mentioned several things about "waived" urine hCG kits that may be of interest.

Patient antibodies may interfere with testing (most common is mouse) giving false positive test results.

There are many hCG isoforms, the one increased the most in pregnancy is the only one small enough to make it through the kidney filter system into the urine. **Specimen of choice for simple pregnancy test = urine.**

The CLIA "waived" urine tests are FDA approved for pregnancy only. Yet, 35% of the testing is used to predict Down's syndrome and 15% as a tumor marker.

✓ **Coagulation sample collection variables:** Melissa Bethel, MT(ASCP), Technical Laboratory Manager for Esoterix Coagulation stated in a presentation to CLIA surveyors at the July, 2008 Western Consortia conference different coagulation tests have different sample requirements. For example, specimens collected for prothrombin time assays (PT) are stable unopened at room temperature for about 24 hours. The sample integrity is enhanced if they are centrifuged immediately.

For activated partial thromboplastin time (APTT), whole blood or processed non-heparinized specimens in an unopened tube at room temperature are stable for up to 4 hours. Heparinized specimens must be centrifuged within one hour and tested within 4 hours. Always check the instrument manual or ask your reference lab for their specific requirements as test methods vary.

✓ **Hemoglobin A_{1c}:** Kristina Jackson Behan, PhD from the Clinical Laboratory Sciences Program at the University of West Florida had an article in the July 2008 issue of Lab Medicine entitled "Improving the Accuracy of Hemoglobin A_{1c}: Your Help Is Needed". She states the ADA recommends new diabetic patients have an A_{1c}, lipid profile, liver function test, urine albumin, and creatinine. Some patients may also need a TSH test before relying on A_{1c} monitoring alone.

When a patient's blood glucose and A_{1c} values do not agree, the A_{1c} is >14%, or consecutive results are very different on different test methods; the National Institutes of Health (NIH) recommend checking the patient for hemoglobin variants.

To improve point of care (POC) testing accuracy, the author recommends initial A_{1c} testing be done by a reference lab capable of detecting the most common hemoglobin variants. If there are no variants, the patient can be monitored with POC methods. She further recommends changing the test reports to reflect the test result, reference range, presence or absence of hemoglobin variants, the name of the analyzer and the variants it is able to detect.

Finally, the International Federation of Clinical Chemistry and Laboratory Medicine recommends changing the reporting units to % HbA_{1c} versus mmol HbA_{1c}/mol Hb in order to standardize test results. Such standardization would minimize result inaccuracies that are caused by other patient conditions such as iron deficiency or hemolytic anemia.

✓ **Preventing Lyme Disease:** The CDC's vector-borne disease branch in Fort Collins, CO has success with a time-released antibiotic mixture in preventing lime disease in mice. The doxycycline hyclate releases the antibiotic over a 20-day period and is 100% effective at preventing Lyme disease. The treatment protects against anaplasmosis (also carried by ticks).

✓ **Independent comparison of Influenza virus A & B rapid detection kits:** In Hiroshima Japan, researchers for the Institute of Public Health and Environment tested nasopharyngeal aspirates from 494 pediatric patients for influenza A and B using 3 different point of care (POC) systems (ESPLINE Influenza A and B-N, Directigen EZ flu A and B, and Binax NOW Influenza A and B). By viral culture, 53 specimens were positive for influenza A and 270 specimens were positive for influenza B. All three kits detected the "A" positive specimens for 100% sensitivity. For the "B" positives, the ESPLINE picked up 86%, the EZ 76% and the NOW 78%. **The catch is the authors used nasal aspirates rather than the nasopharyngeal swabs used in most POC settings**. Other researchers have found lower correlation with swab specimens.

✓ **Clarity Multistrip Urocheck validation:** A multi-site comparison of the Clarity urine dipstick with Bayer's Multistix using the Clinitek Analyzer was summarized in the Summer 2008 edition of Clinical Laboratory Science. The studies in KY, Quebec and IN found Clarity strips had a kappa value above the acceptable 0.85 for nitrite (0.87). All other analytes on the strip were well below the acceptable limits (ranging from 0.00 for color to 0.65 for glucose). The authors conclude the strip will not work on the Clinitek Analyzer.

✓ **Mapping the human microbiome:** We can have as many as 182 bacteria species on a two-centimeter-square patch of skin! The National Institutes of Health (NIH) has $115 million to map the microbial genome of the human body. Some bacteria are necessary to help us digest our food, protect us from pathogen invasion, and synthesize vitamins. Others cause harm and disease. The research will try to distinguish the microbial environment in healthy individuals compared to persons with various diseases to discover which organisms may contribute to poor health.

"You must be the change you wish to see in the world."

Gandhi

☆ Feature ☆

Critical Values

Excerpts from "Reflections on Critical Values" by Teresa P. Darcy, MD, MMM, FASCP at the University of Wisconsin Hospital and Clinics.

After Dr. Darcy's laboratory "participated in a city-wide initiative to reach consensus on a defined list of critical results, it took several years of discussion to determine a process for each type of patient to define how the critical result reached the responsible caregiver."

"Monthly audits of more than 20 percent of laboratory critical results are tracked to the clinical outcome."

Lessons Learned

"One key lesson learned was that each group of stakeholders-physicians, nurses, and laboratory and radiology departments – has a different and strong viewpoint on the *right* way to report critical results. When all the stakeholders agreed in principle that the important viewpoint was that of the patient, we were able to move forward.

The second lesson was that one organization's workflow and process do not necessarily work for another. The temptation was strong to rapidly adopt a process that was being used at

another organization but had no chance for successful implementation at our organization because of our unique aspects and degree of flexibility in meeting regulatory requirements. Organizations differ in infrastructure, size, geographic spread, available communication systems such as paging, and composition of the medical staff.

Third, although the laboratory has the highest volume of critical results to communicate, the organizational discussion and implementation had to be extended to include all diagnostic results.

Finally, the clinical laboratory could not own the entire process of critical result reporting. Tracking the accuracy and timeliness of information handoff from the laboratory was not a surrogate for ensuring that the information would be acted upon by the clinical team."

Challenges

"In the near blizzard of data bombarding the clinical team, the laboratory is faced with many requests to provide more useful information. The physicians would like to have critical value triggers personalized by patient population, by patient condition, or by physician. Requests have been made to call them for all 'significant' results, all 'positive' results, or results that are 'near' critical but have had a significant or rapid change from the last reported measure."

"The challenge is to ensure that the critical information is sent to the person who can act on it. Perhaps the message from the laboratory by phone or paging will be that new critical result information is available."

"The laboratory generates an extraordinary amount of data, and health care systems are looking to laboratory professionals to transform that data into information. I know we can meet that challenge."

Equals
"10 cards: 1 decacards"

CLIA BITS

ADDITIONAL WAIVED TESTS:

° Moore Medical Strep A Test
° Jant Pharmacal Accutest Integrated Strep A Rapid Test
° Inverness Medical BioStar Acceava Strep A Twist
º Henry Schein OneStepPlus Urine Analyzer and One Step+ Strep A Dipstick Test
º Germaine Laboratories Compliance Gold iFOB (fecal occult blood) Test
º Healthcare Provider Direct OneStep Fecal Occult Blood (FOB) Screen Card Test
º BTNX Inc. Rapid Response Immunological Fecal Occult Blood (IFOBT)
º Aventir Biotech LLC Home Check Multiple Drug Cup Test
ºAmerican Bio Medica Rapid TOX
ºCommon Sense Ltd. VA-Sense Kit (pH)

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New addition to CLIA website

You can access "Laboratory Demographic Lookup" from the CLIA website (www.cms.hhs.gov/clia). You can search for laboratories by CLIA number, lab name, geography or application type. Only currently active laboratories are in the database (created 8/25/2008). The BLI website http://health.utah.gov/lab/labimp. will now direct you to the CLIA site.

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CMS issued a memorandum October 17, 2008 revising the requirements for quality control on commercially available microbial identification systems. The new requirements are in line with the CLSI document M50-A "Quality Control for Commercial Microbial Identification Systems" issued August 29, 2008. The document outlines a process to perform streamlined QC according to manufacturer's instructions rather than those found at 42 CFR 493.1256(e)(1).

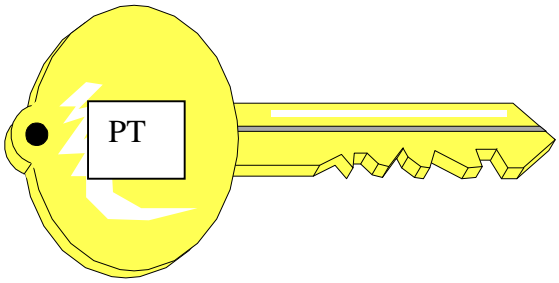
Quality Assessment Spotlight

When patient wristband bar codes at Mount Auburn Hospital in Cambridge kept scanning incorrectly, the POC coordinator set to work finding the "root" cause. "It was the toner we were using to print the wristband" she stated. "It turned out we were using recycled toner in the admitting department's wristband printer. Even one little white dot on one of those bar codes will read as a different number. Luckily, it would not go into the LIS because it wouldn't match with a real patient."

Kudos Deb Phaup, BS(MT), MT(ASCP), CLS (NCA)

Ponderables:

If a deaf person has to go to court, is it still called a hearing?



Proficiency Testing Key Points

- A laboratory performing both manual and automated differentials may enroll for either cell identification or automated WBC differential.
- A certificate of waiver laboratory is not required to enroll.
- Failure to return results in time is considered unsatisfactory performance and the facility is given a zero score for the event.
- Twice yearly verification (for tests not listed in subpart I as requiring PT) may be done using purchased quality control (QC) materials as long as they come from a source other than the daily QC.
- The director can delegate, in writing, signing PT attestation statements to the technical consultant or technical supervisor.
- You may use "additional" sets of PT samples for competency assessment. You may not use a current set for other employees until after you received the graded results evaluation.

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More PT referral cases

In the past 3 months, CMS has notified two Utah laboratories of their findings / sanctions regarding PT referral and PT communication prior to submitting results to the provider.

Also, a state Public Health Laboratory (not Utah) was reported to have sent proficiency samples to a reference laboratory.

These events are very serious and may result in fines or laboratory closure including the director and owner(s) prohibited to own or direct a laboratory for at least two years. This is the 3rd consecutive Bulletin mentioning referral because the incidence is increasing and measures to prevent such occurrences don't appear to be working.

CMS sent a letter to every laboratory director in the country titled: Proficiency Testing (PT) Referral – Risk of Severe Sanctions. Accompanying the letter were 6 pages of frequently asked question about CLIA PT requirements. Information from this letter will be posted on our website http://health.utah.gov/lab/labimp.

SAFETY

Glove Safety Tips

Excerpts from "Gloves: Uncommon Knowledge About Common Objects" by Diane L. Davis, PhD, MT, SC SLS (ASCP), CLS (NCA) in the September 2008 Lab Medicine.

- FDA lowered the acceptable defect rate for exam gloves to 2.5%. So statistically there could be one HIV and one HBV transmission in the US annually from faulty gloves.
- Hot sweaty hands can decrease latex permeability enough in 50 minutes to allow HIV or HBV to penetrate. Change gloves every 30 minutes.
- Nitrile resists perforation better than latex or vinyl, but once perforated the holes enlarge more quickly.
- Chemicals may dissolve gloves enough to allow close skin contact that is more damaging than direct skin contact with the chemical. A fatality from dimethyl-mercury penetration of a latex glove was documented in 1997. Glove manufacturers publish chemical penetration charts.
- It takes about 10 minutes for 100% isopropanol to penetrate latex or vinyl gloves. Some petroleum-based hand lotions can dissolve latex.
- Environmental factors such as ozone, X-rays, ultraviolet light, >91° F, and >40% humidity hasten glove deterioration. Store gloves in a cool, dry, dark area. Discard open boxes after 3 months to maintain glove integrity.
- Latex sensitivity can present with rash, itching and / or respiratory symptoms. Glove powder can make latex particles remain airborne for up to 5 hours.

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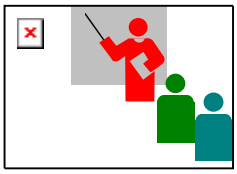
Phlebotomy: Patient alcohol sensitivity

Dennis J. Ernst, MT(ASCP) from the Center for Phlebotomy Education Inc. answered a question in MLO regarding how to disinfect a patient's arm before drawing blood when the patient said they were allergic to alcohol. Mr. Ernst stated:

"Iodine in tincture form, povidone iodine, and chlorhexidine preps all contain ethyl or isopropyl alcohol. So, if you are collecting blood cultures, it would be best to avoid all alcohol-based antiseptics for such patients. Water would be fine, but soap and water would be better. If you can use sterile water, all the better. If you are drawing forensic alcohol levels, just make sure the soap you use does not contain alcohol. Remember, a venipuncture is not considered a sterile procedure unless it is for culture. Nevertheless, it is good infection control to cleanse the site as best you can so as not to spread nosocomial infections. The most important aspects of blood-culture site preparation are 1) to allow the antiseptic to remain in contact with the skin for at least 30 seconds and 2) to provide 30 to 60 seconds of friction to remove dead skin cells, which might

otherwise prevent the antiseptic from coming in contact with the skin flora."

CONTINUING EDUCATION



APHL Teleconferences

"Updates in Diagnostic Detection of Free-Living Amoeba" December 16, 2008 1 PM to 2 PM ET. $75 Call 617.983.6278 or email teleconference@aphl.org for more information.

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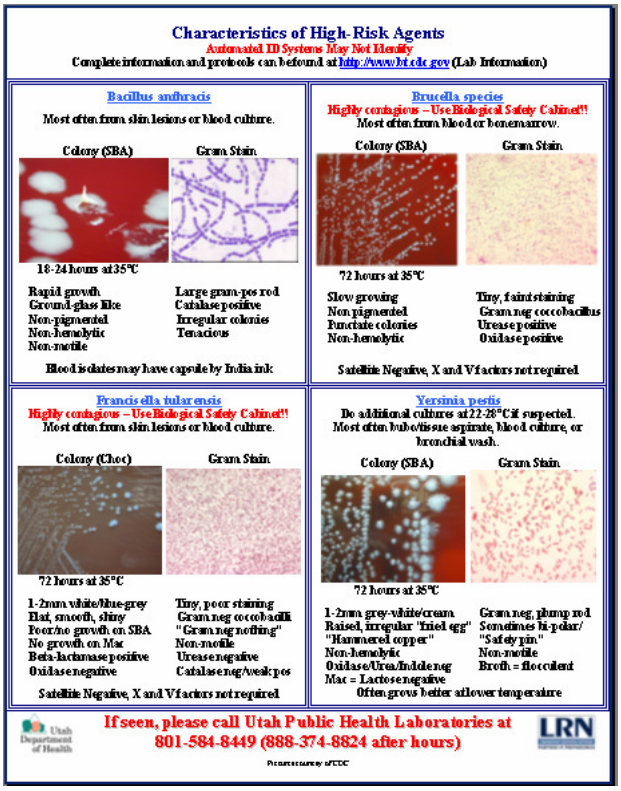
New Sentinel Lab Identification Tool for High-Risk Agents

Utah Public Health Laboratories (UPHL) has created a new visual tool to aid sentinel laboratorians in identifying high-risk agents. This laminated, 8 ½ x 11 inch, double-sided poster includes color pictures and characteristics of certain high-risk bacterial agents and is suitable to post right at the bench. Thanks to George Hinde at Intermountain Medical Center Microbiology lab for this great suggestion!

If your lab would like free copies of this poster, please email/call Kim Christensen (kchriste@utah.gov) or Jana Coombs (jcoombs@utah.gov) at 801-584-8449.

If your lab cannot rule-out one of these high risk agents, please call 801-584-8449 (888-374-8824 after hours).
Complete high-risk agent information and protocols can be found at http://www.bt.cdc.gov (Lab Information).



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Packaging & Shipping Workshop

Reserve March 26, 2009 for a hands-on, all day workshop. The course is presented by Patricia Payne, Ph.D., MT(ASCP) and will meet regulatory requirements for biennial certification. More information will follow next year when the brochures are completed.

Contact Rebecca Christiansen at rchristiansen@utah.gov or 801.584.8471 to reserve a spot. Limited to 25 participants.

Understanding Our Universe

"Technology is a way of organizing the universe so that man doesn't have to experience it."

Max Frisch